

In the Claims:

Please amend the Claims as indicated in the accompanying copy of the Claims. The intended amendments are shown by brackets and underlining. A cleanly-typed copy of the Claims also accompanies this Preliminary Amendment.

REMARKS

This Amendment simply makes slight modifications to the terminology of the Specification to conform the terminology to applicants' issued U.S. Patent 5,674,296, and to commonly accepted terminology in the relevant art. Amendments to the Specification also substitute the issued '296 Patent number for the serial number of the Application from which that patent matured.

No new matter is added by these amendments.

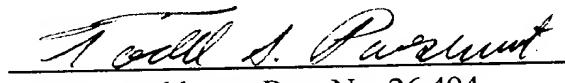
The Amendments to the Claims remedy the likely unpatentability of several claims under 35 USC §112.

More specifically, the Application discloses and claims two embodiments of a drill head used for milling the vertebral bodies of a human spine. One embodiment of the drill head is driven by a shaft and bevel gearing arrangement. The other embodiment of the drill head is driven by a belt arrangement. As readied for issue, the tenth allowed claim seems to be worded so as to call for both a belt drive and a shaft drive in the same embodiment. The depending eleventh and twelfth allowed claims appear to be similarly defective and consequently unpatentable under 35 USC§112. By this Amendment, the dependency of the tenth claim is amended. In this way, specific reference to the shaft drive is provided in one set of dependent claims, and specific reference to the belt drive is provided in a second, separate set of dependent claims.

Finally, the abandonment of the parent application and the filing of this continuation application operates to ask the cognizant examiner to consider the patentability of these claims over the just-discovered U.S. Patent 5,810,827. The '827 patent discloses a bone cutting device. FIGS. 15A and 15B, drawing sheet 12, and FIG. 17, drawing sheet 14 show a milling head capable of milling a concave surface in a bone. The '827 patent does not address the problem of milling such a shape in spaces of small dimension, and it does not suggest applicants' milling head drive systems. A copy of this patent and the requisite form PTO1449 accompany this Preliminary Amendment.

Prompt examination of this Application, allowance, and passage to issue is respectfully solicited.

Respectfully submitted,


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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail No. EM156044455US in an envelope addressed to: Box CPA, Assistant Commissioner for Patents, Washington, DC 20231 on December 30, 1998.

DRILL HEAD FOR USE IN PLACING A[N INTERVERTEBRAL]

VERTEBRAL BODY DISC DEVICE

This is a Continuation of U.S. Patent Application No. 08/944,235 filed October 6, 1997.

Background of the Invention

This invention relates generally to drill heads and more particularly to drill heads for use in placing a[n intervertebral] vertebral body disc device.

The herniation of a spinal disc and the often resultant symptoms of intractable pain, weakness, sensory loss, incontinence and progressive arthritis are among the most common of debilitating processes affecting mankind. If a patient's condition does not improve after conservative treatment, and if clear physical evidence of nerve root or spinal cord compression is apparent, and if correlating radiographic studies (i.e., MRI or CT imaging or myelography) confirm the condition, surgical removal of the herniated disc may be indicated. The process of discectomy -- as the name implies -- involves the simple removal of the disc without attempt to replace or repair the malfunctioning unit. In the United States in 1985, over 250,000 such operations were performed in the lumbar spine and in the cervical spine.

Statistics suggest that present surgical techniques are likely to result in short-term relief, but will not prevent the progressive deterioration of the patient's condition in the long run. Through better pre-operative procedures and diagnostic studies, long-term patient results have improved somewhat. But it has become clear that unless the removed disc is replaced or the spine is otherwise properly supported, further degeneration of the patient's condition will almost certainly occur.

In the mid-1950's and 60's, Cloward and Smith & Robinson popularized anterior surgical approaches to the cervical spine for the treatment of cervical degenerative disc disease and

related disorders of the vertebrae, spinal cord and nerve root; these surgeries involved disc removal followed by interbody fusion with a bone graft. It was noted by Robinson (Robinson, R. A.: The Results of Anterior Interbody Fusion of the Cervical Spine, *J. Bone Joint Surg.*, 440A: 1569 1586, 1962) that after surgical fusion, osteophyte (bone spur) reabsorption at the fused segment might take place. However, it has become increasingly apparent that unfused vertebral segments at the levels above and below the fused segment degenerate at accelerated rates as a direct result of this fusion. This has led some surgeons to perform discectomy alone, without fusion, by a posterior approach in the neck of some patients. However, as has occurred in surgeries involving the lower back where discectomy without fusion is more common as the initial treatment for disc herniation syndromes, progressive degeneration at the level of disc excision is the rule rather than the exception. Premature degenerative disc disease at the level above and below the excised disc can and does occur.

Spine surgery occasionally involves fusion of the spine segments. In addition to the problems created by disc herniation, traumatic, malignant, infectious and degenerative syndromes of the spine can be treated by fusion. Other procedures can include bone grafts and heavy duty metallic rods, hooks, plates and screws being appended to the patient's anatomy; often they are rigidly and internally fixed. None provide for a patient's return to near-normal functioning. Though these procedures may solve a short-term problem, they can cause other, longer term, problems.

A number of attempts have been made to solve some of the problems described above by providing a patient with spinal disc prostheses, or artificial discs of one sort or another. For example, Steffee, U.S. Patent 5,031,437, describes a spinal disc prosthesis having upper and

lower rigid flat plates and a flat elastomeric core sandwiched between the plates. Frey et al., U.S.

Patents 4,917,704 and 4,955,908, disclose [intervertebral] vertebral prostheses, but the prostheses are described as solid bodies.

U.S. Patents 4,911,718 and 5,171,281 disclose resilient disc spacers, but no inter-connective or containing planes or like elements are suggested, and sealing the entire unit is not taught.

[Co-pending, related U.S. Patent Application Serial No. 08/681,230] U.S. Patent No.5,674,296, incorporated herein by reference, provides a vertebral disc endoprosthesis which addresses these shortcomings of the prior art. The endoprosthesis comprises a resilient body formed of a material varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion. A concaval-convex means at least partly surrounds that resilient body so as to retain the resilient body between adjacent vertebral bodies of a patient's spine. If medical considerations so indicate, several disc endoprosthesis can be combined with one or more endoprosthetic vertebral bodies in an entire assembly.

In order to place the above endoprosthesis in a patient's spine, the bone of the two opposing [intervertebral] vertebral bodies must be prepared in such a manner so as to accept the concaval-convex shape of endoprosthesis. However, currently available drill heads are not always capable of being fit into the narrow space between two opposing [intervertebral] vertebral bodies. Further, the narrow space between two opposing [intervertebral] vertebral bodies cannot always be expanded to allow admittance of currently available drill heads.

Thus, it is an object of the instant invention to provide a drill head which can fit within

the narrow space between two opposing [intervertebral] vertebral bodies.

It is another object of the instant invention to provide a drill head which can prepare the bone of the two opposing [intervertebral] vertebral bodies to accept the concaval-convex shape of an endoprosthesis.

These and other objects and advantages of the instant invention will be apparent from the following description and drawings.

Summary of the Invention

The instant invention overcomes the deficiencies of the prior art devices by providing a drill head with a narrow profile which can fit in the space between two opposing [intervertebral] vertebral bodies.

The drill head of the instant invention is provided with a form cutter having a convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis.

Brief Description of the Drawings

Figure 1 is a side view of one embodiment of the instant invention.

Figure 2 is a cross-sectional view of the embodiment of Figure 1.

Figure 3 is a partial cross-sectional view of an alternate embodiment of the instant invention.

Detailed Description of the Invention

While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and

equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

One embodiment of the drill head of the present invention is depicted in Figures 1 and 2. The drill head 20 generally comprises a form cutter portion 22, drive means 24, and attachment means 26. In accordance with the invention, the form cutter profile imparts a shape to the bone of the [intervertebral] vertebral bodies which mates with the predetermined endoprosthesis surface shape.

As seen in Figure 2, the drill head 20 includes a form cutter 29 carried by a housing 31 having an upstanding wall 35 and a shaft support 37 for supporting the form cutter 29. The housing 31 further includes an elongated shaft portion 40 which houses the drive shaft discussed below. To provide a drill head which can prepare the bone of the two opposing [intervertebral] vertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter 29 has a convex milling surface 42. This convex surface 42 of the form cutter 29 functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of U.S. Patent No. 5,674,296 [co-pending U.S. Patent Application Serial No. 08/681,230].

The form cutter 29 further includes an outwardly and upwardly extending edge 44 about its perimeter. In addition, the undersurface 47 of the form cutter 29 may be provided with a beveled gearing surface 49. Alternately, the beveled gearing surface 49 may be provided about the undersurface of the upstanding edge.

The form cutter 29 is provided with a shaft 51 extending perpendicularly from its undersurface. The form cutter 29 is supported within the housing 31 by the cooperation between

the shaft 51 and the shaft support 37. This arrangement permits the form cutter 29 to be removed from the housing 31 by separating the shaft 51 from the shaft support 37. Thus, when the cutter dulls, it can be replaced with a new cutter to ensure accurate and effective performance of the drill head.

In order to provide a drill head which can fit within the narrow space between two opposing [intervertebral] vertebral bodies in accordance with the invention, the maximum height of the illustrated form of the cutter portion 22 of the drill head 20 is nine millimeters. Providing the bevel gearing surface 49 on the form cutter 29 allows the drill head 20 to be manufactured with such a narrow profile. This arrangement eliminates the need for a separate gear and form cutter which would likely add to the height of the drill head. Because of its profile, the drill head 20 of the present invention can fit in the narrow space between two opposing [intervertebral] vertebral bodies in the cervical spine of a patient.

To provide a driving force to the form cutter 29, the drill head 20 is provided with drive means 24. As shown in Figure 2, the drive means 24 comprises a drive shaft 54 operatively coupled at its distal end to the form cutter 29 and at its proximal end to a drive source 61. The distal end of the drive shaft 54 is supported by a journal 56 within the housing and is provided with a pinion gear 59. As mentioned above, the undersurface 47 of the form cutter 29 is provided with a beveled gearing surface 49. When the drive shaft 54 rotates, the pinion gear 59 also rotates and cooperates with the beveled gearing surface 49 of the form cutter 29, thereby causing the form cutter 29 to rotate about the shaft 51.

The proximal end of the drive shaft 54 is operatively coupled to a suitable drive source 61 by coupling means 63. Although a drive source is not shown in the embodiment of Figures 1 and

2, it should be understood that the drive source shown by Figure 3 or its functional equivalent could be employed. The illustrated drive source 61 comprises a suitable motor 65 having mating coupling means 69. The motor 65 imparts a driving force to the drive shaft 54 via the mating of the coupling means 63, 69.

As shown in Figure 2, the form cutter 29 is not necessarily oriented at a right angle with respect to the drive shaft 54. In the illustrated device, the angle between the support shaft 51 of the form cutter 29 and the drive shaft 54 is approximately 96° to provide a designed orientation to the vertebral bone surface being milled.

The housing 31, which houses the form cutter 29 and the drive shaft 54, is provided at its proximal end with an attachment means 71. The attachment means 71 allows the drive source to be attached to the drill head 20 of the present invention. In the embodiment of Figure 2, the drive source is attached to the drill head 20 via threads 73. However, alternate equivalent attaching means could be employed to attach the drive source to the drill head 20. The housing 31 is also provided with a ring 75 about its circumference.

An alternate embodiment of the drive means 24 used in the drill head is shown in Figure 3. Rather than being driven by a gear and pinion mechanism, the drill head 20 is driven by a drive belt 78. To accommodate the belt driving arrangement, the form cutter 29 is provided with a groove 80 about its perimeter rather than being provided with a beveled gearing surface. The groove 80 interacts with the drive belt 78 to provide a driving force to the form cutter 29. This alternate driving arrangement enables the drill head 20 to be manufactured with a narrow profile.

As mentioned above, in this embodiment of the invention, the drive means 24 comprises a drive belt 78 which is operatively coupled to the form cutter 29 at the distal end of the drill

head 20. The belt 78 loops around the form cutter 29 within the groove 80. At the proximal end of the drill head 20, a drive shaft 82 is provided which is operatively coupled to a suitable drive source 61. The drive shaft 82 is provided with a pulley 85 about which the belt 78 is looped. At one end, the drive shaft 82 is supported by the housing 31 with suitable means such as a bearing or bushing 87. At its opposite end, the drive shaft 82 is provided with a coupling means 63 for coupling to a suitable drive source 61. When the drive source 61 acts upon the drive shaft 82 and causes it to rotate, the pulley 85 is caused to rotate, thereby driving the belt 78 and causing the form cutter 29 to rotate.

To accommodate the driving means arrangement of this alternate embodiment, the housing 31 is provided with a perpendicular extension 90 at the proximal end of the drill head 20. The extension 90 is provided with the attachment means 71 for attaching the drill head 20 to a suitable drive source 61. It is within the extension 90 that the drive shaft 82 is coupled to the drive source 61. The housing extension 90 is further provided with an intermediate support member 92 for providing additional support to the drive shaft 82.

Claims

1. A drill head for preparing the bone of two opposing [intervertebral] vertebral bodies to accept a predetermined shape of an endoprosthesis comprising:
a form cutter having a profile capable of imparting a shape to the bone of [intervertebral]
vertebral bodies which mates with the predetermined endoprosthesis surface shape;
drive means for providing a driving force to the form cutter, and
means for housing the form cutter and the drive means,
wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing [intervertebral] vertebral bodies.
2. The drill head of Claim 1 wherein the form cutter has a convex shape.
3. The drill head of Claim 2 wherein the form cutter is provided with a beveled gearing surface.
4. The drill head of Claim 2 wherein the form cutter is provided with a groove about its perimeter.
5. The drill head of Claim 1 wherein the drive means comprises a drive shaft operatively coupling the form cutter to a drive source.
6. The drill head of Claim 5 wherein a distal end of the drive shaft is provided with a pinion gear which cooperates with the form cutter to impart a rotary motion to the form cutter.
7. The drill head of Claim 5 wherein a proximal end of the drive shaft is provided with a coupling means for coupling the drive shaft to the drive source.
8. The drill head of Claim 1 wherein the drive means comprises a belt operatively coupling the form cutter to a drive source.

9. The drill head of Claim 8 wherein the belt loops about the perimeter of the form cutter.

10. The drill head of Claim 1 [8] wherein the drive means further comprises a drive shaft operatively coupled to the belt.

11. The drill head of Claim 10 wherein the drive shaft is provided with a pulley about which the belt is looped.

12. The drill head of Claim 11 wherein the drive shaft is further provided with a coupling means for coupling the drive shaft to the drive source.

13. The drill head of Claim 1 wherein the housing is provided with attachment means for attaching the drill head to a drive source.

14. The drill head of Claim 1 wherein the maximum height of the profile of the form cutter is approximately nine millimeters.

15. A drill head for preparing the bone of two opposing [intervertebral] vertebral bodies to accept the concaval-convex shape of an endoprosthesis comprising:

a form cutter having a support shaft capable of imparting a concave shape to the bone of [intervertebral] vertebral bodies;

drive means for providing a driving force to the form cutter, the drive means including a drive shaft; and

means for housing the form cutter and the drive means,

wherein the angle between the support shaft of the form cutter and the drive shaft is approximately 96°.

16. The drill head of Claim 15 wherein the form cutter has a predetermined profile.
17. The drill head of Claim 16 wherein the maximum height of the profile of the form cutter is approximately nine millimeters.

Abstract

A drill head for preparing the bone of two opposing [intervertebral] vertebral bodies to accept the concaval-convex shape of an endoprosthesis includes a form cutter portion, drive means, and a housing. The form cutter having such a profile allows the drill head to fit in the narrow space between two opposing [intervertebral] vertebral bodies in the cervical spine of a patient.